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SPECIFICATION FOR STEAM STERILIZERS

PART 2 HORIZONTAL CYLINDRICAL HIGH SPEED STEAM STERILIZERS, PRESSURE TYPE

(*First Revision*)

First Reprint September 1991
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NEW DELHI 110002

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August 1979

Indian Standard

SPECIFICATION FOR STEAM STERILIZERS

PART 2 HORIZONTAL CYLINDRICAL HIGH SPEED STEAM STERILIZERS, PRESSURE TYPE

(First Revision)

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Indian Standard
SPECIFICATION FOR STEAM STERILIZERS
PART 2 HORIZONTAL CYLINDRICAL HIGH SPEED STEAM STERILIZERS, PRESSURE TYPE
(First Revision)

0. FOREWORD

0.1 This Indian Standard (*First Revision*) was adopted by the Indian Standards Institution on 21 November 1978, after the draft finalized by the Hospital Equipment Sectional Committee had been approved by the Consumer Products and Medical Instruments Division Council.

0.2 The formulation of Indian Standards on hospital equipment has been taken up at the instance of the Advisory Committee for the Development of Surgical Instruments, Equipment and Appliances of the then Ministry of Industry and Supply, Government of India.

0.3 This Indian Standard was first published in 1968 and now it has been revised keeping in view the latest developments in the manufacture of pressure type high speed steam sterilizers. This revised standard allows the use of mild steel doors for stainless steel chambers of the sterilizers. This revision also takes into account the two amendments issued from time to time.

0.4 This specification provides for equipment supplied with built-in steam generator, electrically heated. It is suggested that tap water, reasonably free from scale-forming constituents, should be used for steam generation. If the water is hard it should be treated before it is used for steam raising (*see also* IS : 1690-1968*).

0.5 Adequate provisions have been made throughout the standard for the safety and satisfactory design of the apparatus, bearing in mind the fact that a good deal of latitude is to be allowed to the individual manufacturer of sterilizers to introduce innovations and refinements.

0.6 The problem of explosion arising from fumes of anaesthetic agents have not been taken into consideration on the understanding that all

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*Code of practice for treatment of water for land boilers (*first revision*).

types of sterilizers dealt within this standard would be installed, generally remote from the anaesthetizing area in the operation theatre, and that the anaesthetic room would be outside the zone of explosion risk. Installation of these sterilizers in an operation theatre is not recommended.

0.7 This standard covers, by and large, the performance aspects of sterilizers. Dimensions of component parts have not been specified. It is recognized that some parts of the sterilizers may have to be replaced during use. For this reason it is essential that the manufacturers should so design their sterilizers that the spare parts of any particular size are interchangeable within one's manufacture.

0.8 In the preparation of this standard assistance has been derived from:

BS 3219 : 1960 Horizontal Cylindrical Hospital Sterilizers : Pressure Steam Type. British Standards Institution.

BS 3220 : 1960 Horizontal Rectangular Hospital Sterilizers : Pressure Steam Type. British Standards Institution.

GG-S-00751e (VAMED) Interim federal specification for sterilizers, horizontal pressure type, non-portable. Bureau of Federal Supply, Government Printing Office, USA.

0.9 This standard contains clauses **5.1**, **5.4**, **6.3**, **9.3**, **10.1** and **13.1** which call for agreement between the purchaser and the supplier and which permit the purchaser to use his option for selection to suit his requirements.

0.10 This standard recognize a period of six minutes for emergency sterilization of unwrapped surgical instruments. This period stands for one complete cycle of operation which includes time taken for charging the sterilizer and covering the contents after sterilization. The actual sterilization (exposure time) taken being three minutes or so.

0.11 For the purpose of deciding whether a particular requirement of this standard is complied with, the final value, observed or calculated, expressing the result of a test or analysis, shall be rounded off in accordance with IS : 2-1960*. The number of significant places retained in the rounded off value should be the same as that of the specified value in this standard.

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*Rules for rounding off numerical values (*revised*).

1. SCOPE

1.1 This standard specifies requirements for non-automatic or automatic process control, jacketed, pressure steam sterilizers of horizontal cylindrical type, designed for working pressure of 220 kN/m^2 (2·2 kgf/cm^2 approx) gauge but shall be set to operate at $210^{+0}_{-0\cdot15}$ kN/m^2 ($2\cdot1^{+0}_{-0\cdot15}$ kgf/cm^2 approx) gauge pressure (corresponding temperature of the saturated steam inside the chamber about 134°C) primarily intended for emergency sterilization of unwrapped surgical instruments within six minutes.

2. TERMINOLOGY

2.1 Sterilizer — For the purpose of this standard the sterilizer shall mean a steam pressure appliance, used for the destruction of bacteria and related organisms.

3. DESIGN

3.1 The sterilizer shall consist of a chamber with an annular steam jacket on the sides. The chamber shall have a door at one end.

3.2 The sterilizer shall be designed to operate on steam from an attached steam generator (boiler) heated by electricity.

3.3 The sterilizer shall be capable of performing the following operations constituting one full cycle of sterilization with load:

a) Generate steam and build up working pressure in the jacket without admitting it to the chamber;

b) Admit steam to the chamber and allow it to build up to working pressure, and temperature (maintaining the pressure in the jacket) and retaining the working temperature for at least 15 minutes;

c) Exhausting the chamber pressure while retaining the jacket pressure; and

d) Drying of load in chamber (if required) through the circulation of dry and filtered air entering through a drying system as specified in **7.1.5**.

4. SHAPE AND SIZE

4.1 Shape — Sterilizers shall have a circular cross-section forming the receptacle.

4.2 Size — The size of a sterilizer shall be determined by the size of the inside of the chamber generally conforming to Fig. 1.

5. MATERIAL

5.1 Various components of the sterilizers shall be fabricated from combinations of materials given in Appendix A. The recommended uses of the sterilizers depending on the combinations of materials are also given in Appendix A. The sterilizers, in addition, shall satisfy the requirements specified in **5.2** and **5.3**.

NOTE — Due to non-availability of mild steel plates according to IS : 2041 - 1962*, the use of boiler quality tested mild steel plate shall be permitted till such time the above steel is available indigenously.

5.2 When the seams and the pipe connections are soldered or brazed it shall be done with oxy-acetylene, oxy-propane, air-acetylene, or air propane flame.

5.3 In stainless steel sterilizers all joints shall be welded by Argon arc process or with appropriate flux coated electrodes.

5.4 Piping — All piping shall be from non-corrosive materials like stainless steel, brass, copper, etc. Brass or copper piping shall be seamless or brazed if required by the purchaser. Piping of stainless steel or clad material may have a welded seam.

6. CONSTRUCTION

6.1 The sterilizers shall consist of a chamber with an annular steam jacket. The construction of the shell (chamber, jacket, back plate and end ring) shall be in accordance with best practice and joints fusion-welded. Typical cylindrical construction is shown in Fig. 1.

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*Specification for steel plates for pressure vessels.

6.2 Shell — The general arrangement of the four shell components (*see* **6.1**) shall be as indicated in Fig. 1.

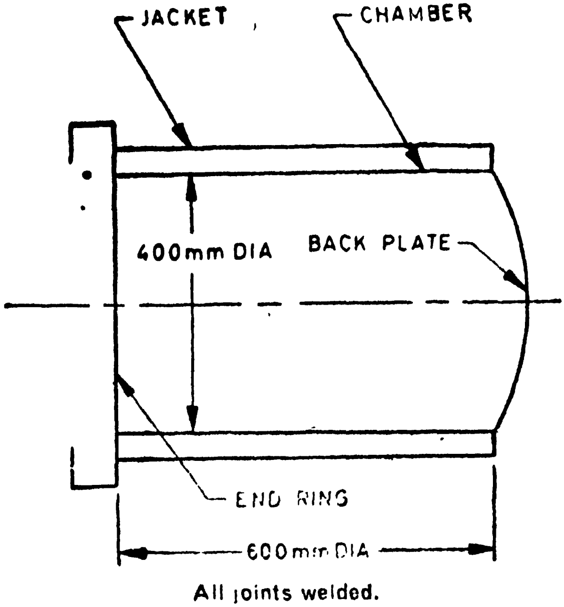

FIG. 1 STERILIZER, CYLINDRICAL

6.2.1 The number of sheets or plates required to form the chamber and jacket shall not exceed two each. All seams shall be butt fusion welded (*see* IS : 2825-1969*). When the shell is made from more than one width of plate, the longitudinal seams shall not fall in one line.

6.2.2 The back plate shall always be formed out of one sheet.

6.2.3 Each shell shall have at least the following connectors welded:

a) One for operative valve;
b) One for safety valve;
c) Two for steam inlet for the steam generator, attached to the sterilizer;
d) One for chamber drain;
e) One for steam inlet to chamber; and
f) One for vacuum drier.

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*Code for unfired pressure vessels.

6.2.3.1 The material of the connector shall be the same as that of the member of shell to which it is welded.

6.2.4 All outer surfaces of the jacket shall be suitably insulated (lagged). Further the insulation shall be covered suitably.

6.3 Door — The door shall be fitted on one side of the shell and open sideways normally to the right side, facing the sterilizer unless otherwise specified by the purchaser. The inside portion when made of mild steel sheet shall have a thin coating of zinc metallizing (about 10 microns) or may be coated with heat resisting paint.

6.3.1 *Locking Device*—A door locking device shall be so arranged that when opening and closing the door, the locking arms or members are fully engaged before gasket seal can be established to ensure effective sealing. The door shall lock positively when the pressure in the chamber is 30 kN/m^2 (0·30 kgf/cm^2 approx) gauge or more and the lock shall not get released till the pressure falls below this level. Provision shall be made to tighten the door while in locked position.

6.3.2 *Door Gasket* — It shall be one-piece without joint and moulded of steam-resistant and resilient material like neoprene. It shall be capable of effectively sealing the door against internal pressure up to the hydraulic test pressure. The gasket material shall be durable enough to withstand the working temperature over long periods.

6.3.3 *Adjustment* — All doors shall have a device incorporated, capable of adjustment when misaligned.

7. FITTING

7.1 The following shall be provided on sterilizers.

7.1.1 *Operating Valve* — Sterilizers shall be provided with a single multiport valve which shall control the cycle of sterilization consisting of the following operations:

a) Preserving pressure in jacket without admitting it to chamber till needed;
b) Admitting steam to chamber, but maintaining the jacket pressure;
c) Exhausting the chamber of steam but maintaining jacket pressure;
d) Circulating dry and filtered air for drying but maintaining the jacket pressure; and
e) Exhausting the jacket and boiler of steam.

7.1.1.1 The operating valve shall be located in the front of the sterilizer and shall be easily accessible.

7.1.2 ***Exhaust Time*** — It shall be possible to exhaust the chamber in one minute. If need be, an additional valve may be provided.

7.1.3 *Safety Valve* — Where a pressure switch for electric operation for controlling pressure is provided on the boiler, one spring-loaded safety valve shall be provided to the jacket.

7.1.3.1 Where the safety valve also acts as relief valve to regulate the operating pressure, an additional safety valve, either spring or weight-loaded, shall be provided. It shall be so constructed as to prevent an increase in the steam pressure of more than 10 percent of the pressure, at which the relief valve is set to lift. It shall shut down at a pressure not more than 10 percent below the pressure at which the valve is set to lift.

7.1.4 ***Vacuum Breaker*** — The jacket shall be provided with an automatic device to admit air to jacket in the event of formation of vacuum in the jacket due to steam condensation.

7.1.5 ***Drying System*** — The filter supplied with the drying system shall admit filtered air to the chamber and shall entrain vapours and odours to be conducted to exhaust. The filter supplied shall be of the ceramic labyrinth type with a maximum pore size of 50 microns of a cast column containing at least 15 g of tightly-packed nickel-copper alloy wool.

7.1.6 ***Baffle*** — For effective distribution of steam in the chamber a baffle of non-corrosive metal or a sparge pipe shall be fitted to distribute steam effectively throughout the chamber.

7.1.7 ***Chamber Drain*** — The sterilizer chamber shall be fitted with one or more chamber drain lines for thorough evacuation of air condensate from the chamber during the steam exposure stage of the sterilizing cycle. The drain line shall be fitted with a thermostatic steam trap and a check valve. The bore shall be such as to allow evacuation of air within 2 minutes of introduction of steam.

7.1.7.1 ***Plug screen*** — The chamber end of the drain line shall have an easily removable plug screen to prevent large particles from entering and clogging the line.

7.1.7.2 *Thermometer* — The chamber drain line shall be fitted with a temperature measuring device which shall be mercury thermometer or dial type thermometer readable from the front of the sterilizer. When a dial thermometer is provided the minimum diameter of the dial shall be 60 mm with an accuracy of 1·5°C at any reading.

7.1.8 *Gauges* — Sterilizers shall be fitted with pressure gauge to indicate the jacket pressure and a compound pressure-vacuum gauge to indicate the pressure in the chamber. Both gauges shall be easily readable from the front of the sterilizer.

7.1.9 *Automatic Process Control Unit* — If required by the purchaser, an automatic process control unit with temperature and/or pressure recorder may be provided to control the sterilization cycle mentioned in **3.3** automatically.

7.1.9.1 The above sterilization cycle shall satisfy an appropriate heat sensitive tape test.

8. HYDROSTATIC TEST

8.1 On completion of manufacture, the sterilizer chamber shall be subjected to a hydrostatic test of one and a half times, and the sterilizer jacket to twice the working pressure.

8.1.1 The jacket shall be tested at atmospheric pressure in the chamber. The test pressure shall be maintained for not less than 20 minutes during which all accessible parts shall be examined; there shall be no sign of leakage, sweating, weakness or permanent deformation.

8.2 The steam generating boiler shall be subjected to hydrostatic test of twice the working pressure of the sterilizer. Test pressure shall be maintained for not less than 20 minutes and during this time all the accessible parts shall be examined. There shall be no sign of leakage, sweating, temporary or permanent deformation.

9. METHOD OF STEAM SUPPLY TO STERILIZERS

9.1 Source of Supply — Steam shall be supplied to sterilizers from a built-in steam generator, heated electrically.

9.2 Built-in Steam Generator — This steam generator shall be attached to the underside of the shell, with two steam inlet pipes to the jacket.

These inlet pipes may also act as supports for the steam generator. It shall be capable of easy disconnection for cleaning. It shall be cylindrical in construction and all joints shall be butt fusion welded in accordance with best practice of welding for pressure vessels.

9.2.1 Steam generators shall be provided with a gauge glass of wall thickness at least 1 mm to indicate water level, and self-locking gauge glass valves in case of accidental breakage of gauge glass under pressure.

9.3 **Electric Heating** — The steam generator shall be electrically heated by immersion heaters wired for operation on 3-phase 4-wire, 400/440 V, 50 Hz ac supply or any other supply, if specifically required by the purchaser. The electric load for this type of sterilizer shall be 18 kW. The heaters shall be easily accessible. A switch shall be provided on the control panel to isolate the heaters from the mains.

9.3.1 *Low Water Protection* — Low water protection for heaters shall be provided to cut off electric supply to heaters through a contactor if the water level runs below the heater level.

9.3.2 *Pressure Control* — Working pressure should preferably be controlled through a pressure switch connected preferably to the steam generator or to the jacket, but not to the chamber.

9.3.3 *Switch Box* — The contactor, switches and pilot lights shall be located in one box mounted either on the stand of the sterilizer or on an adjacent wall.

9.4 **Capacity** — The capacity of the steam generator of the sterilizer shall be sufficient to give two complete emergency cycles of sterilization, each cycle lasting approximately six minutes.

10. ACCESSORIES

10.1 When specified by the purchaser, the following accessories shall be provided.

10.1.1 *Loading Carriage and Trolley* — The carriage shall be suitable for loading the particular type or types of loads specified by the purchaser. The carriage shall roll on rails fixed to the chamber. The rails shall also be of the same material as the chamber.

10.1.1.1 The carriage shall roll-in and roll-out freely on a trolley mounted on robust wheels or castors. The trolley shall have provision for locking the carriage and shall have arrangement to lock itself on the sterilizer during loading and unloading.

10.1.2 *Trays or Racks* — Trays or racks shall be provided in the chamber of the size, shape and material as agreed to between the purchaser and the manufacturer.

10.1.2.1 In case of racks for instruments, the rack shall contain at least three removable trays made of stainless steel.

10.1.3 *Thermograph* — Sterilizers shall have arrangement in the chamber drain line to fit a thermograph at any time. The thermograph when supplied may be operated electrically or mechanically by a spring motor.

10.1.3.1 The thermograph chart shall be graduated on the Celsius scale. The thermograph shall record temperatures over a period of 24 hours. Lock and key arrangement shall be provided on the door of the thermograph.

10.1.4 *Flush Mounting* — Sterilizers shall be arranged for installation through a wall to expose the door and the necessary operating handles and instruments on one side. The rest of the sterilizer shall lie on the other side.

10.1.4.1 The sterilizer shall be provided with a panel as specified by the purchaser to be mounted in the front, flush with the wall.

10.1.4.2 All extended valve spindles shall be supported through metallic sleeves.

10.1.5 *Water Injector* — A suitable manual device shall be provided to refill water in steam generator when the latter is under steam pressure.

11. MARKING

11.1 Each sterilizer shall be legibly and indelibly marked with the following:

a) Identification of the manufacturer;

b) Code and serial number;

c) Working pressure;

d) Hydrostatic test pressure; and

e) Wattage, voltage, phase and cycle.

11.1.1 The sterilizer may also be marked with the Standard Mark.

NOTE — The use of the Standard Mark is governed by the provisions of the *Bureau of Indian Standards Act, 1986* and the Rules and Regulations made thereunder. The Standard Mark on products covered by an Indian Standard conveys the assurance that they have been produced to comply with the requirements of the standard under a well defined system of inspection, testing and quality control which is devised and supervised by BIS and operated by the producer. Standard marked products are also continuously checked by BIS for conformity to that standard as a further safeguard. Details of conditions under which a licence for the use of the Standard Mark may be granted to manufacturers or producers may be obtained from the Bureau of Indian Standards.

12. OPERATIVE MANUAL

12.1 Each sterilizer shall be accompanied by an operating manual which shall contain the following information:

a) Instructions and plan for installation of the sterilizer;

b) Operation of the sterilizer;

c) Routine maintenance service;

d) Steam penetration time for various packaged loads; and

e) Materials used or combination of a material used for chamber and jacket.

13. PACKING

13.1 Each sterilizer shall be packed as agreed to between the purchaser and the manufacturer.

APPENDIX A

(*Clause* 5.1)

MATERIALS TO BE USED IN THE FABRICATION OF STERILIZERS

A-1. COMBINATIONS FOR CHAMBER AND JACKET AS RECOMMENDED FOR USE OF STERILIZERS

Chamber		*Jacket*		*Recommended Use*
Material	Conforming to	Material	Conforming to	
Stainless steel	Designation 04Cr18Ni10 or 04Cr17Ni12 Mo2 and of 2B finish in accordance with Table 8 of IS : 6911-1972[*]	Stainless steel	Designation 04Cr18Ni10 and of 2B finish in accordance with Table 8 of IS : 6911-1972[*] or	Chamber steel 04Cr18Ni10 for dressings, linen and instruments; and chamber steel 04Cr17Ni12 Mo2 for crystalloids like saline
		Mild steel	IS : 2041 - 1962[†]	

A-2. COMPONENTS

Sl No.	*Component*	*Material*	*Conforming to*
1.	Precision hexagonal headed bolts, nuts and screws	—	IS : 2389-1968[‡]
2.	Nuts and bolts	Stainless steel	Designation 07Cr18Ni9 or 04Cr18Ni10 of IS: 1570 (Part V) - 1972[§]
3.	Door	Gun metal or	IS : 306-1968[‖] or Grade 1 or 2 of IS : 318-1962[¶]
		Stainless steel or	Same as for the chamber
		Mild steel	IS : 2041-1962[†]
4.	Door ring	Forged steel or	IS : 2002-1962[**]
		Stainless steel	Same as for the chamber

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[*] Specification for stainless steel plate, sheet and strip.

[†] Specification for steel plates for pressure vessels.

[‡] Specification for precision hexagonal bolts, screws, nuts and lock nuts (dia range 1·6 to 5 mm) (*first revision*).

[§] Schedules for wrought steels for general engineering purposes: Part V Stainless and heat-resisting steels (*first revision*).

[‖] Specification for tin bronze ingots and casting (*second revision*).

[¶] Specification for leaded tin bronze ingots and castings (*revised*).

[**] Specification for steel plates for boilers.

A-3. COMPOSITIONS OF STAINLESS STEEL LISTED IN A-1 AND A-2

Constituent	04Cr18Ni10 Percent	07Cr18Ni9 Percent
Carbon	0·08, *Max*	0·12, *Max*
Silicon	1·0, *Max*	1·0, *Max*
Manganese	2·0, *Max*	2·0, *Max*
Nickel	8·0 to 12·0	8·0 to 10·0
Chromium	17·0 to 20·0	17·0 to 19·0

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